What Is Claimed Is:

1. A pharmaceutical composition, comprising:

(a) a KGF-2 polypeptide in a concentration range of about 0.02 to about 40 mg/ml (w/v);

(b) a buffer having a buffering capacity of about pH 5.0 to about pH 8.0 at a concentration range of about 5 mM to about 50 mM; and

(c) a pharmaceutically acceptable diluent to bring the composition to a designated volume; and

(d) a preservative selected from the group consisting of m-cresol, chlorobutanol, and a mixture of methyl paraben and propyl paraben;

or a reaction product thereof.

2. The pharmaceutical composition of claim 1, further comprising one or more of:

(a) a chelating agent at a concentration range of about 0 mM to about 10 mM; and

(b) a tonicifier at a concentration range of about 0 mM to about 150 mM.

3. The pharmaceutical composition of claim 2, wherein said tonicifier is selected from the group consisting of NaCl, glycine, sucrose, mannitol, and mixtures thereof.

4. The pharmaceutical composition of claim 1, further comprising one of:

1. about 0.5% to about 2% w/v glycerol,
2. about 0.1% to about 1% w/v methionine, or
3. about 0.1% to about 2% w/v monothioglycerol.

5. The pharmaceutical composition of claim 1, wherein said KGF-2 polypeptide is present in a concentration range of about 0.05 to about 30 mg/ml (w/v).

6. The pharmaceutical composition of claim 5, wherein said KGF-2 polypeptide is present in a concentration range of about 0.1 to about 20 mg/ml (w/v).

7. The pharmaceutical composition of claim 6, wherein said KGF-polypeptide is present in a concentration range of about 0.2 to 4 mg/ml.

8. The pharmaceutical composition of claim 1, wherein said KGF-2 polypeptide is KGF-2- Δ33.

9. The pharmaceutical composition of claim 1, wherein said diluent is water.

10. The pharmaceutical composition of claim 2, wherein said chelating agent is EDTA at a concentration of about 1 mM, and said tonicifier is present at a concentration of about 125 mM.

11. The pharmaceutical composition of claim 1, wherein said pH is from about pH 5.5 to about pH 6.5.

12. The pharmaceutical composition of claim 11, wherein said pH is about pH 6.0.

13. The pharmaceutical composition of claim 1, wherein said buffer is selected from the group consisting of phosphonic, acetic, aconitic, citric, glutaric, malic, succinic carbonic acid, and an alkali or alkaline earth salt thereof.

14. The pharmaceutical composition of claim 13, wherein said buffer is a phosphate, acetate or citrate salt.

15. The pharmaceutical composition of claim 13, wherein said buffer is a citrate salt.

16. The pharmaceutical composition of claim 1, wherein said buffer is present in a concentration range of about 5 mM to about 30 mM.

17. The pharmaceutical composition of claim 16, wherein said buffer is a citrate salt present in a concentration of from about 10 mM to about 20 mM.

18. The pharmaceutical composition of claim 1, further comprising a stabilizing amount of one or more of (a) an antioxidant or (b) a thiol-compound.

19. The pharmaceutical composition of claim 1, wherein said composition is maintained at a temperature at or below -20°C.

20. The pharmaceutical composition of claim 1, wherein said KGF-2 Δ33 polypeptide is selected from the group consisting of KGF-2 Δ33 polypeptide having an N-terminal methionine, KGF-2 Δ33 polypeptide lacking an N-terminal methionine, and a mixture thereof.

21. The pharmaceutical composition of claim 1, further comprising a bulking agent.

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~~22~~. The pharmaceutical composition of claim 21, wherein said bulking agent is selected from the group consisting of sucrose, glycine, mannitol, trehalose, and mixtures thereof.

27 25. The pharmaceutical composition of claim 22, wherein said bulking agent is sucrose or a mixture of sucrose and glycine.

24. The pharmaceutical composition of claim 2, further comprising a bulking agent.

25. The pharmaceutical composition of claim 22, wherein said bulking agent is present in a concentration of about 2% to about 10% w/v.

26. The pharmaceutical composition of claim 22, wherein said bulking agent is 5% mannitol, 7% sucrose, 8% trehalose, or 2% glycine + 0.5% sucrose.

27. The pharmaceutical composition of claim 21, wherein said pH is about pH 6.2.

28. The pharmaceutical composition of claim 21, wherein said diluent is water.

29. The pharmaceutical composition of claim 21, wherein said buffer is selected from the group consisting of phosphonic, acetic, aconitic, citric, glutaric, malic, succinic carbonic acid, and an alkali or alkaline earth salt thereof.

30. The pharmaceutical composition of claim 29, wherein said buffer is a phosphate or citrate salt.

31. The pharmaceutical composition of claim 30, wherein said buffer is a citrate salt.

32. The pharmaceutical composition of claim 28, wherein over 90% of the water is removed by lyophilization.

32 ~~33~~. The pharmaceutical composition of claim ~~32~~ 30, which is reconstituted in with an amount of sterile water effective to maintain isotonic conditions of about 290 mOsm.

34. The pharmaceutical composition of claim 21, wherein said KGF-2 polypeptide is KGF-2-Δ33. a

35. The pharmaceutical composition of claim 34, wherein said KGF-2 Δ33 polypeptide is selected from the group consisting of KGF-2 Δ33 polypeptide having an N-terminal methionine, KGF-2 Δ33 polypeptide lacking an N-terminal methionine, and a mixture thereof. b

36. The pharmaceutical composition of claim 21, wherein said buffer is added in a concentration from about 5 mM to about 50 mM

37. The pharmaceutical composition of claim 36, wherein said buffer is citrate at a concentration of about 10 mM.

38. The pharmaceutical composition of claim 21, further including a stabilizing amount of one or more of (g) an antioxidant, or (h) a thiol-compound.

31 ~~39~~. The pharmaceutical composition of claim ~~32~~ 30, wherein said composition is reconstituted in sterile water containing a stabilizing amount of an antioxidant comprising: a) about 0.01% to about 2% w/v monothioglycerol, b) about 0.01% to about 2% w/v ascorbic acid, c) about 0.01% to about 2% w/v methionine or d) combinations thereof.

39 31 ~~40~~. The pharmaceutical composition of claim 1, further comprising a thickening agent in an amount effective to raise the viscosity to about 50 to about 10,000 cps.

40 ~~41~~. The pharmaceutical composition of claim ~~40~~ 39, wherein said thickening agent is present in an amount effective to raise the viscosity to about 50 to about 1,000 cps.

41 ~~42~~. The pharmaceutical composition of claim ~~41~~ 40, wherein said thickening agent in an amount effective to raise the viscosity to about 200 to about 300 cps.

42 ~~43~~. The pharmaceutical composition of claim ~~40~~ 39, wherein said thickening agent is present in a concentration of 0 to 5% (w/w).

44. The pharmaceutical composition of claim 40, wherein said thickening agent is a water soluble etherified cellulose or a high molecular weight polymer of acrylic acid cross-linked with allylsucrose or an allyl ether of pentaerythritol.

49 ~~45~~. The pharmaceutical composition of claim ~~44~~ 48, wherein said etherified cellulose is an alkyl cellulose, hydroxyalkyl cellulose, carboxyalkyl cellulose or alkylhydroxyalkyl cellulose.

~~46~~. The pharmaceutical composition of claim 40, wherein said etherified cellulose is methylcellulose, hydroxyethyl cellulose, hydroxy propyl cellulose, hydroxy propyl methylcellulose, or carboxymethyl cellulose.

51 ~~47~~. The pharmaceutical composition of claim ~~46~~ 50, wherein said etherified cellulose derivative has a molecular weight of about 50,000 to about 700,000 and is present in a concentration of about 0 to about 20% by weight.

52 ~~48~~. The pharmaceutical composition of claim ~~47~~ 51, wherein said etherified cellulose derivative has a molecular weight of about 80,000 to about 240,000 and is present in a concentration of about 2% to about 8% by weight.

42 ~~45~~. The pharmaceutical composition of claim ~~42~~ 41, wherein said buffer is citrate in a concentration of about 10 mM to about 50 mM.

43 ~~50~~. The pharmaceutical composition of claim ~~49~~ 42, wherein said buffer is citrate in a concentration of about 10 mM to about 20 mM citrate.

44 ~~51~~. The pharmaceutical composition of claim ~~49~~ 42, wherein said bulking agent is sucrose in a concentration of about 0.01% to about 5% sucrose.

45 ~~52~~. The pharmaceutical composition of claim ~~51~~ 44, wherein said thickening agent is added directly to a liquid formulation and thereafter lyophilized.

46 ~~53~~. The pharmaceutical composition of claim ~~51~~ 44, wherein said thickening agent is added to a lyophilized formulation by reconstituting said formulation by adding a suitable diluent having a thickening agent dissolved therein.

~~54~~ 23. The pharmaceutical composition of claim 21, further comprising a thickening agent in an amount effective to raise the viscosity to about 50 to about 10,000 cps.

~~55~~ 53. The composition of claim 1, further comprising a gelling agent in an amount effective to raise the viscosity to about 0.1 to about 10,000 cps at room temperature.

~~56~~ 22. The composition of claim 21, further comprising a gelling agent in an amount effective to raise the viscosity to about 0.1 to about 10,000 cps at room temperature.

54 ~~57~~. The composition of claim ~~55~~ 53, wherein said gel forming agent is a water-soluble polymer capable of forming a viscous aqueous solution, or non-water soluble, water-swellable polymer capable of forming a viscous solution.

55 ~~58~~. The composition of claim ~~57~~ 54, wherein said gel forming agent is a high molecular weight polymer selected from the group consisting of vinyl polymer, polyoxyethylene-polyoxypropylene copolymer, polysaccharide, protein, poly(ethylene oxide), acrylamide polymer or a salt thereof.

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~~59~~. The composition of claim 58, wherein said gel forming agent is (1) a vinyl polymer selected from the group consisting of polyacrylic acid, polymethacrylic acid, polyvinyl pyrrolidone polyvinyl alcohol, and salts and esters thereof; or (2) a polysaccharide selected from the group consisting of a cellulose derivative, a glycosaminoglycan, agar, pectin, alginic acid, dextran, α-amylose, amylopectin, chitosan, and salts esters thereof.

57 ~~60~~. The composition of claim ~~58~~ 55, wherein said gel forming agent is a glycosaminoglycan selected from the group consisting of hyaluronic acid, chondroitin, chondroitin-4-sulfate, heparan sulfate, heparin and salts and esters thereof.

58 ~~61~~. The composition of claim ~~60~~ 57, wherein said glycosaminoglycan is present in combination with collagen, gelatin, or fibronectin.

59 ~~62~~. The composition of claim ~~58~~ 55, wherein said gel forming agent is an acrylamide polymer selected from the group consisting of a polyacrylamide or a polymethacrylamide.

60 ~~63~~. The composition of claim ~~58~~ 55, wherein said gel forming agent is a polyoxyethylene-polyoxypropylene block copolymer.

64. The composition of claim 63, which comprises about 10 to about 60% by weight of a polyoxyethylene-polyoxypropylene block copolymer having an average molecular weight of about 500 to 50,000.

65. The composition of claim 64, which comprises about 14 to about 18% by weight of a polyoxyethylene-polyoxypropylene block copolymer having a molecular weight in the range 1,000 to 15,000.

66. The composition of claim 1, wherein said KGF-2 polypeptide is present in a concentration of about 0.01 mg/ml to about 10 mg/ml.

67. The pharmaceutical composition of claim 1, wherein said KGF-2 polypeptide is a N-terminal deletion selected from the group consisting of Ala (63) -- Ser (208) (KGF-2Δ28) and Ser (69) -- Ser (208) (KGF-2Δ33).

68. The pharmaceutical composition of claim 67, wherein said KGF-2 polypeptide has an N-terminal methionine, lacks an N-terminal methionine, or is a mixture thereof.

69. The pharmaceutical composition of claim 1, wherein said KGF-2 polypeptide is a N-terminal or C-terminal deletion mutant selected from the group consisting of Ala (39) -- Ser (208); Pro (47) -- Ser (208); Val (77) -- Ser (208); Glu (93) -- Ser (208); Glu (104) -- Ser (208); Val (123) - Ser (208); Gly (138) -- Ser (208); Met (1), Thr (36); and Cys (37) -- Lys (153).

70. The pharmaceutical composition of claim 69, wherein said KGF-2 polypeptide has an N-terminal methionine, lacks an N-terminal methionine, or is a mixture thereof.

71. The pharmaceutical composition of claim 1, further comprising one of:

(a) lysine;

(b) hydroxypropyl-β-cyclodextrin; and

(c) sulfated-β-cyclodextrin;

or combinations thereof.

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~~72~~. The pharmaceutical composition of claim 1, wherein said preservative is a mixture of methyl paraben and propyl paraben.

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~~73~~. The pharmaceutical composition of claim ~~72~~ 65, wherein said composition comprises 0.18% methyl paraben and 0.02% propyl paraben.

74. A pharmaceutical composition comprising:

(a) about 1.0 mg/ml KGF-2;

(b) 20 mM citrate, pH 5-5.5; and

(c) 0.01% polysorbate 80.

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~~75~~. The pharmaceutical composition of claim ~~74~~ 67, further comprising 1 mM EDTA.

76. A pharmaceutical composition comprising:

(a) about 3.3 mg/ml KGF-2;

(b) 10 mM sodium citrate

(c) 20 mM sodium chloride;

(d) 1 mM EDTA

(e) 2% w/v glycine;

(f) 0.5% w/v sucrose;

(g) water; and

(h) pH about 6.2;

or a reaction product thereof.

77. The pharmaceutical composition of claim 77, wherein over 90% of the water is removed by lyophilization.

78. A pharmaceutical composition comprising:

(a) about 1.0 mg/ml KGF-2;

(b) 0.46% hydroxyethylcellulose;

(c) 7% sucrose;

(d) 20 mM sodium citrate;

(e) 20 mM sodium chloride;

(f) 1 mM EDTA; and

(g) pH about 6.2;

or reaction products thereof.